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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097009,846	01/20/98	ZAMBIAS	R 5925-061-999

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HM22/0503

EXAMINER
PONNALURI, P

ART UNIT	PAPER NUMBER
1618	15

DATE MAILED: 05/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/009,846

Applicant(s)
Zambias et al

Examiner
P. Ponnaluri

Group Art Unit
1618



☒ Responsive to communication(s) filed on Mar 18, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

KEITH D. MacMILLAN
PRIMARY EXAMINER

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The substitute amendment filed on 3/18/99 has been fully considered and entered into the application.
3. Claims 1-15 are currently pending in this application.
4. In the specification page 1, applicants are suggested to amend the current status of the parent application 08/375,838.
5. Art references listed by applicant on Form 1449 filed on 5/15/98, were not considered by the examiner because copies of these references can not be found in the instant application or parent application serial number 08/375,838.
6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: signature of one of the inventors is missing.
7. The petition to correct the inventor ship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted.

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8. The disclosure is objected to because of the following informalities: In specification page 16, specification discloses that the arrays are tested for IND candidacy. It is not clear what does applicant mean by "IND", does applicant mean that IND means 'Investigational New Drug'. Applicants are requested to clarify.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a logically ordered, spatially addressable array of different compounds having same molecular core comprising at least three atoms of carbon, oxygen, nitrogen, sulfur, or phosphorus, and at least two structural diversity elements; methods of making the array; and method of screening the array. The specification disclosure is insufficient to enable one skilled in the art to practice the invention without undue amount of experimentation. The specification disclosure does not have sufficient guidance to which core compounds and which structural diversity elements are used to make the instant array. The specification disclosure fails to teach what are structurally diversity elements are. The claims also recite that the molecular

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cores have attachment points, ability to present the structural diversity elements, but the specification does not have guidance which of the compounds form the core molecules. The breadth of claims encompass any compound which has carbon, or nitrogen or sulfur, oxygen or phosphorus as core molecules, and the specification does not have sufficient guidance on how to select these core molecules. The specification also teaches that the instant arrays are useful in screening or synthesis of other compounds. The specification does not disclose any screening assays in which the compounds of the array are screened. The specification fails to give adequate guidance in selecting an assay in which the array of compounds are screened and there are no working examples of screening assays in which the instant arrays are screened for biologically active compounds. It is also not clear which assays one would use to screen the instant array as recited because the instant array does not recite any known specific compounds or compounds of known activity. Thus it would require undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The instant specification discloses soluble libraries, which are useful for screening. The specification fails to show the

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claimed array of compounds are analogous to any compound with recognized activity. However, the utility asserted by the applicants on page 16 of the specification is not a specific utility because it involves basic research utilizing the compounds in a method for studying the properties of the compounds itself. The specification teaches that the libraries can be screened for biological activity and/or physical activity and the present invention would be a tool for preparation and rapid synthesis of compounds and additional structural related compounds, screening and testing of compounds for IND candidacy. However the specification does not disclose any specific receptor or any particular biological process to screen the library. Thus the asserted utility requires basic research upon the material itself and the specification does not disclose any specific utility, hence credibility of the utility can not be assessed. In the absence of any data, these libraries are deemed to be not supported by a specific asserted utility.

12. Claims 1-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims are drawn toward logically-ordered, spatially addressable array of different compounds. The disclosure teaches that the instantly recited array is useful as screening tools (see page 16). The specification teaches that the array can be screened for rapid synthesis, screening and testing of compounds for IND candidacy and the arrays may be assembled to form super array for exhaustive testing, but does not disclose any specific or particular biological

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process. The specification has not disclosed a single assay method how biologically active compounds or lead compounds are identified from the array. The specification also does not identify any specific assay. The specification disclosure fails to give sufficient guidance and direction in selecting an assay in which the libraries would be useful or would even be believed to be useful based upon a relationship to a known class of active compounds. The person skilled in the art would require undue amount of experimentation to practice the claimed invention. The specification fails to provide any working examples of screening assay methods in which the libraries of the instant application have been used to screen the biologically active compound. The breadth of the claims encompass any number and/or type of compounds and the specification is silent as to which may be beneficial or detrimental to employ. The specification disclosure does not disclose any biologically active compound as a result of the claimed array. In view of the nature of the invention, the amount of guidance present in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 8, 10 and 11 are vague and indefinite by reciting 'logically ordered', 'spatially-addressable array of compounds'. It is not clear what does applicant mean by logically ordered, spatially addressable array. It is not clear how the compounds in the array differ from each other in the spatially addressable array, since the molecular core of the compounds is the same, and the structural diversity elements are not defined. It is also vague and indefinite by reciting 'an ability to present the structural diversity elements in controlled varying arrangements, and an ability to be constructed in a rapid concerted fashion...', it is not clear which one (molecular core or the structural diversity element or the array) has the ability to be constructed in a rapid concerted fashion, and able to present the structural diversity elements and it is also not clear what does applicant mean by controlled varying arrangements.

Claims 8 and 10 are vague and indefinite by reciting 'the first and second sub-arrays are different', this is not clear since the claim recites that the array has different compounds comprising same molecular core, and the first and second sub-arrays have the same structural diversity element, how will the first and second array are different. Applicants are requested to clarify.

Claim 10 is vague and indefinite by reciting 'a) providing a plurality of reaction vessels organized into the first and subarray...', it is not clear how the reactants will be added to the vessels in the subarray form the compounds of the array. The subarrays are separated by the vessels, how will they form a single array. Does applicant refer to each subarray as an array. It is very confusing. Applicants are suggested to clarify.

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Claim 11 is vague and indefinite by reciting 'apportioning into reaction vessels that are identifiable by their spatial addresses', it is not clear what does applicant mean by spatial address, does it mean the location of the vessel or some kind of numbering. Claim 11 is also vague by reciting '.....the first plurality of comprising a same first ...', Applicants are suggested to amend the claim. The step b) in the claim does it mean that all the first and second compounds in each reaction vessels are added together into one so that one single array of compounds is formed, applicants are requested to clarify.

Claim 12 is vague and indefinite by reciting '.....formatting the contents of the reaction vessels into a spatially-addressable array.', it is not clear how the contents of the reaction vessels is formatted into spatially addressable array. Does it mean that after the reactions are completed the compounds are rearranged.

Claims 14-15 are vague and indefinite by reciting 'a property of interest', it is not clear what property of interest is.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the compound of interest is identified, i.e., contacting the array of compounds with a target.

15. No claims are allowed.

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The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.


Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams, can be reached at (703)308-0570. The fax number for this group is (703)308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0916.

P. Ponnaluri

April 29, 1999


KEITH D. MacMILLAN
PRIMARY EXAMINER